K113066

510(k) SUMMARY
Oculus Optikgeraete GmbH
Corvis ST

NOV 8 2012

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: November 7, 2012

Name of Device and Name/Address of Sponsor

Corvis ST

Oculus Optikgeraete GmbH
Muenchholzhaeuser Strasse 29
35582 Wetzlar
Germany

Common or Usual Name

Non-Contact-Tonometer (Product Code HKX), Pachymeter (Product Code MXK)

Classification Name

21 C.F.R. §886.1930, Tonometer (AC Powered), Analysis, Anterior Segment

Predicate Devices

Nidek Incorporated, Non-Contact-Tonometer NT 1000 (K913189)
Oculus Optikgeraete GmbH, Pachycam (K041841)

Intended Use / Indications for Use

The Corvis ST is intended to measure the intra-ocular pressure of the eye in patients with less than 3 diopters of corneal astigmatism. In addition, the Corvis ST is designed to photograph the eye and take Scheimpflug images of the anterior segment of the eye to evaluate the thickness of the cornea.

Technological Characteristics

The Corvis ST performs the following two functions:

Tonometry
The Corvis ST measures intraocular pressure without contact with the eye by applying an air puff to the eye. The eye is illuminated and during the air puff, a high-speed camera records the movement of the eye with more than 4000 images per second. The high-speed camera analyzes a sequence of 140 Scheimpflug images of the cornea to determine intra-ocular pressure.

Pachymetry
The Corvis ST measure corneal thickness and shape based on sectional images when the cornea is not influenced by the air puff. The pachymetry measurements of the Corvis ST and the cleared Oculus predicate use the same image processing routine for analysis to obtain corneal thickness measurements.

Tonometry and pachymetry functions can be performed during the same evaluation or separately.

Performance Data

Clinical Data – Pachymetry

The "Side-by-side testing of Central Corneal thickness (Apex): Corvis ST vs. Pachycam" was an internal study to evaluate the correlation between the measurement data of the FDA cleared device Pachycam (K041841) and the Corvis ST.

The study evaluated the apical thickness of the cornea in the center (Pachymetry). Both eyes of each subject were measured and every eye was measured three times on the same device.

The number of subjects was 51, so 102 eyes were examined. In the study, subjects were chosen with corneal thicknesses from 463 µm to 635 µm.

Results:
The correlation coefficient of the representative apical thickness value was > 0.98. The overall mean (+/- standard deviation) difference of the Corvis ST apical thickness measurements to the Pachycam was -0.10 ± 4.48 µm. The within-eye repeatability (standard deviation) of the Corvis ST for each set of triplicate results per eye per subject was calculated to be 3.03 µm.

Clinical Data – Tonometry
Testing was performed in conformance with ANSI Z80.10-2009 (in accordance with FDA´s extent of recognition) and EN ISO 8612:2009.

The aim of this evaluation was to compare the intraocular pressure (IOP) results measured by the Corvis ST tonometer with those obtained by the Goldmann applanation tonometer (Haag-Streit) over three IOP-groups.

Results:

Difference IOP (Corvis ST) – IOP (GAT)				
Group	**Number of eyes**	**IOP (mmHg)**	**Difference Corvis ST to reference tonometer (GAT)**	**Within limits (5mmHg)**
1	40	7 - 16	0.8 ± 2.3 mmHg	39 (97.5 %)
2	40	> 16 - < 23	-0.5 ± 2.2 mmHg	38 (95 %)
3	40	≥ 23	0.3 ± 2.5 mmHg	39 (97.5 %)
total	120	7-48	0.2 ± 2.4 mmHg	116 (96.7 %)

The mean deviation between the test tonometer and the reference tonometer was 0.2 ± 2.4 mmHg. 96.7 % of the investigated eyes were within the limits of ± 5 mmHg, no eye had a deviation to the reference tonometer of more than 7.5 mmHg.

The Corvis ST meets all the requirements EN ISO 8612:2009 and to ANSI Z80.10-2009 (in accordance with FDA´s extent of recognition) if eyes with astigmatism >3 D are excluded in accordance with EN ISO 8612:2009. The agreement between the Corvis ST and the Goldmann applanation tonometer (GAT) is satisfactory, with a standard deviation of the difference between the Corvis measurement and the Goldmann measurement of 2.4 mmHg.

Bench Testing – Tonometry

The company performed tonometric testing to evaluate the accuracy and reproducibility of the Corvis ST in its intended measuring range in accordance with FDA's extent of recognition section 4.2.3 "Bench Assessments of Bias and Precision" of ANSI Z80.10-2009, Ophthalmic Instruments – Tonometers (Ophthalmic). The testing was performed by measuring a manometric controlled test eye, which consisted of a membrane enclosed with a water filled pressure chamber. The pressure in the test chamber was adjusted by a hydrostatic head and controlled manometrically by an attached calibrated pressure sensor as reference. The measurements were taken using the Corvis ST device and additionally verified by a reference tonometer.

Results:

In the tonometry bench test, the correlation coefficient of the representative IOP value was > 0.99. The overall difference of the Corvis ST measurements to the manometric adjusted pressure values was -0.26 ± 1.1 mmHg. The test bench results show that none of the paired differences between the reference tonometer reading and the test tonometer reading for each manometric adjusted pressure value are greater than +/- 5 mmHg and also that none of the paired differences between the reference tonometer reading and the test tonometer reading for each pressure range are greater than +/- 7.5 mmHg.

Bench Testing – Pachymetry

The focus of this internal study was to demonstrate that the performance data of the Corvis ST is accurate and reproducible over the complete stated measurement range of 300 µm - 1200 µm. The testing was performed by measuring several glass plates with several known thicknesses, known scattering, and known refraction indices.

Results:

In the pachymetry bench test, the correlation coefficient of the representative pachymetry value was > 0.99. The overall difference of the Corvis ST measurements to the reference thickness values was -0.43 ± 3.85 µm.

Substantial Equivalence

The Corvis ST is substantially equivalent to the predicate devices. The Corvis ST has the same intended use, technological characteristics, and principles of operation as its predicate devices. Bench and clinical testing demonstrate substantially equivalent performance to the predicates. The minor technological differences between the Corvis ST and its predicate raise no new issues of safety and effectiveness. Performance data demonstrate that the Corvis ST is as safe and effective as the predicate devices. Thus, the Corvis ST is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

NOV 8 2012

OCULUS Optikgeraete GmbH
% Mr. Eckhard Loh
Regulatory Affairs Manager
Munchholzhauser Str. 29
Wetzlar
Germany D-35582

Re: K113066
Trade/Device Name: OCULUS Corvis® ST model 72210
Regulation Number: 21 CFR 886.1930
Regulation Name: Tonometer, AC-powered
Regulatory Class: Class II
Product Code: HKX, MXK
Dated: October 24, 2012
Received: October 24, 2012

Dear Mr. Loh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113066

Device Name: Corvis ST

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean C Callaway

(Division Sign-Off)

Division of Ophthalmic, ~~Neurological~~ and Ear, Nose and Throat Devices

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